**Longwood University Biological Research Registration**

**Appendix A: Section III of the NIH Guidelines**

**RECOMBINANT DNA EXPERIMENTS COVERED UNDER NIH GUIDELINES**

This appendix summarizes the five categories of experiments involving recombinant DNA that are listed in the NIH Guidelines. The guidelines should be consulted for additional information at <http://oba.od.nih.gov/rdna/nih_guidelines_oba.html>.

**Section III-A. Experiments that require Institutional Biosafety Committee approval, Recombinant DNA Advisory Committee (RAC) review, and NIH Director approval before initiation of the experiment.**

* III-A-1. Major actions under the NIH Guidelines (See Appendix D of the NIH Guidelines).
	+ III-A-1a. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally, if such acquisition could compromise the use of the drug to control disease agents in human or veterinary medicine or agriculture.

**Section III-B.** **Experiments that require NIH/ORDA and Institutional Biosafety Committee approval before the initiation of the experiment.**

* III-B-1. Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as tetanus toxin).

**Section III-C. Experiments that require Institutional Biosafety Committee and Institutional Review Board approvals and NIH/ORDA registration before initiation of experiments.**

* III-C-1. Experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects.

**Section III-D. Experiments that require Institutional Biosafety Committee approval before initiation of experiments.**

* III-D-1. Experiments using human or animal pathogens (Risk Group 2, 3, or 4) as host vector systems.
	+ III-D-1a. Experiments involving the introduction of recombinant DNA into Risk Group 2 agents carried out at BSL-2 containment.
* III-D-2. Experiments in which DNA from human or animal pathogens (Risk Group 2, 3, or 4) is cloned in nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
	+ III-D-2a. Experiments in which DNA from Class 2 or Class 3 Agents is transferred into nonpathogenic prokaryotes or lower eukaryotes carried out at BSL-2 containment. The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BSL-1.
* III-D-3. Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence helper virus in tissue culture systems.
	+ III-D-3a. Experiments involving the use of infectious or defective Risk Group 2 animal viruses in the presence of helper virus performed at BSL-2 containment.
* III-D-4. Experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.
	+ III-D-4a. Recombinant DNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BSL-1 and appropriate to the organism under study.
	+ III-D-4b. Experiments involving recombinant DNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III-D-1 or III-D-4a, carried out at the appropriate containment determined by the Institutional Biosafety Committee.
	+ III-D-4c. Exceptions under Section III-D-4
		- III-D-4c(1). Experiments involving the generation of transgenic rodents that require BSL-1 containment are described under section III-E-3.
		- III-D-4c(2). The purchase or transfer of transgenic rodents is exempt from the NIH Guidelines under section III-F.
* III-D-5. Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes,(e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA, conducted under the containment conditions described in Sections III-D-5a through III-D-5e.
* III-D-6. Experiments involving more than 10 liters of culture. The appropriate containment will be decided by the Institutional Biosafety Committee.

**Section III-E. Experiments that require Institutional Biosafety Committee notice simultaneously with initiation.**

* III-E-1. Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus.
* III-E-2. Experiments involving whole plants that are not covered under any other section of the Guidelines.
	+ III-E-2a. BSL-1-P is recommended for all experiments with recombinant DNA-containing plants and plant-associated microorganisms not covered in Section III-E-2b or other sections of the NIH Guidelines. Examples of such experiments are those involving recombinant DNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area, and experiments involving whole plants and recombinant DNA-modified non-exotic microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., *Rhizobium* spp. and *Agrobacterium* spp.).
	+ III-E-2b. BSL-2-P OR BSL-1-P + biological containment is recommended for the following experiments:
		- III-E-2b(1). Plants modified by recombinant DNA that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.
		- III-E-2b(2). Plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent.
		- III-E-2b(3). Plants associated with recombinant DNA-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems.
		- III-E-2b(4). Plants associated with recombinant DNA-modified exotic microorganisms that have no recognized potential for serious detrimental impact on natural ecosystems.
		- III-E-2b(5). Experiments with recombinant DNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant DNA-modified microorganisms associated with them if the recombinant DNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems.
* III-E-3. Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BSL-1 containment are covered under this section. Other experiments are covered under section III-D-4.

**Section III-F. Experiments that are exempt from NIH Guidelines. Review and/or approval from the Institutional Biosafety Committee is not necessary.**

* III-F-1. Recombinant DNA molecules that are not in organisms or viruses.
* III-F-2. Recombinant DNA molecules that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
* III-F-3. Recombinant DNA molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species) or when transferred to another host cell by well established physiological means.
* III-F-4. Recombinant DNA molecules that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or closely related strain of the same species).
* III-F-5. Recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes though one or more of the segments may be a synthetic equivalent.
* III-F-6. Recombinant DNA molecules which do not present a significant risk to health or the environment, as determined by the NIH.